

PATENT COOPERATION TREATY

From the:

INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

04 OCT 2004

21 JUL 2004

To:

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Level 15
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PCT

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY EXAMINATION
REPORT

(PCT Rule 71.1)

Date of mailing
day/month/year 20 JUL 2004

Applicant's or agent's file reference
12187260/TDO/LM

IMPORTANT NOTIFICATION

International Application No.
PCT/AU2003/000403

International Filing Date
2 April 2003

Priority Date
2 April 2002

Applicant

MONASH UNIVERSITY et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide

Name and mailing address of the IPEA/AU

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PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 12187260/TDO/LM	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU2003/000403	International Filing Date <i>(day/month/year)</i> 2 April 2003	Priority Date <i>(day/month/year)</i> 2 April 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ C07K 014/415; A61K 038/16; A61P 037/08		
Applicant MONASH UNIVERSITY et al		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of 4 sheets, including this cover sheet. <div style="margin-left: 20px;"> <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). </div> <div style="margin-left: 20px;"> These annexes consist of a total of sheet(s). </div>
3.	This report contains indications relating to the following items: <div style="margin-left: 20px;"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application </div>

Date of submission of the demand 3 October 2003	Date of completion of the report 15 July 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer R.L. POOLEY Telephone No. (02) 6283 2242

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 7, 8, 11-16, 19, 20, 26, 27, 31-39	YES
	Claims 1-6, 9, 10, 17, 18, 21-25, 28-30, 40-47	NO
Inventive step (IS)	Claims	YES
	Claims 1-47	NO
Industrial applicability (IA)	Claims 1-47	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1: WO 1996/000238 A1 (PEPTIDE THERAPEUTICS LIMITED) 04 January 1996, see claims.

D2: Burton et al, J. Allergy Clin. Immunol., vol. 103, no. 2, part 1, 1999, pages 255-261, see page 256, column 1.

D3: WO 1997/005258 A2 (BIOMAY PRODUKTIONS) 13 February 1997, see abstract.

D4: Ball et al, FASEB Journal, 1999, Vol. 13(11), pages 1277-1290, see abstract.

D5: Eusebius et al, Int Arch Immunol 2002, Vol. 127, pages 234-244, see page 243, final paragraph.

Novelty (N)

Citation D1 discloses polypeptides including XVXRIDTXX of Lol p 1, which is part of sequence ID number 24 of the current application. The citation also treats rye grass allergy by administration of said polypeptide. Thus claims 1, 3-6, 9, 17-18, 21-25, 28-30 and 40-47 lack novelty.

Citation D2 discloses Lol p 5, p105-116 with a view to identifying analogues that could be used as immunotherapeutic agents against rye grass pollen allergic disease. Claims 2, 10, 21 and 40-47 thus lack novelty.

Claims 7, 8, 11-16, 19, 20, 26, 27 and 31-39 relate to peptides containing amino acid sequences not specifically disclosed in the citations, and thus these claims are novel.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V**Inventive Step (IS)**

Citations D3-5 do not specifically disclose Lol p 1 or Lol p 5. They do however disclose epitopes of grass pollens and their use in immunotherapy against allergic reactions to said pollens. Given that Lol p 1 and Lol p 5 are well known to a person skilled in the art (see D1 and D2), no inventive faculty is required to use either epitope in the treatment or prevention of rye grass allergy. Citations D1 and D2 are particularly relevant as the use of one of Lol p 1 or Lol p 5 would easily lead a person skilled in the art to try the other. Thus all claims lack an inventive step when compared to citations D1-D5.

Industrial Applicability (IA)

All claims possess industrial applicability.